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Sonya J. Bible

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Does The Experimental-Use Defense to Patent Infringement Still Exist?

*Sonya J. Bible**

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* Sonya J. Bible is registered patent attorney with principal office in Dallas, Texas. She received her J.D. from Texas Wesleyan University School of Law in 2006 and an LL.M. in Intellectual Property and Information Law from the University of Houston Law Center in 2007.

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I. INTRODUCTION AND SUMMARY

We currently live in a world increasingly reliant on technological innovation where the innovation of one entity is often improved upon and advanced by the improvements and ingenuity of another. Where earlier innovations are protected by patents, the innovators of later improvements must design around the claims of the previous patents or seek licenses from the owners of the previous patents in order to lawfully make improvements. In this way, innovators can protect their inventions, and the public is enriched by a disclosure that enables others to make and use at least one version of the invention. In turn, this encourages further innovation.

The origins of the rights of patent holders can be traced to Article 1, section 8, clause 8 of the U.S. Constitution, which endeavors “to promote the progress of . . . useful arts by securing for a limited times to . . . inventors the exclusive rights to their . . . discoveries.”¹ Under current patent law, the owner of a U.S. patent is granted the right to exclude others from making, using, selling, offering to sell, or importing all configurations of products that are within the claim language.² If these rights are violated, the patent owner can sue for infringement.³ In response, an alleged infringer will most often attempt to invalidate the patent.⁴ The alleged infringer may also assert affirmative defenses to the infringement claim.⁵

One of these defenses is that the asserted making, using, etc., was for purely experimental purposes, and should not count as an act of infringement for that reason. Whether this is a valid defense in law is the subject of this paper. The patent statute does not address this issue, except in the case of experiments for purposes of FDA approval.⁶ A more general exemption has been the subject of great debate, and recent case law calls the general exemption into question. One such case is *Madey v. Duke*, decided by the Federal Circuit in 2002. The court ruled that a university’s use of a patented machine for experimentation was still a commercial use, and therefore, not exempt from an infringement claim.⁷ Another opinion, *Integra Lifesciences I, Ltd. v.*

1. U.S. CONST. art. 1, § 8, cl. 8.

2. 35 U.S.C. § 154(a)(1) (2000).

3. 35 U.S.C. § 271(a)-(b).

4. 35 U.S.C. §§ 102-03.

5. See, e.g., 35 U.S.C.A. §§ 102-03 (2000) (various ways to invalidate a patent). There are numerous other affirmative defenses employed as well.

6. 35 U.S.C. § 271(e)(1).

7. *Madey v. Duke Univ.*, 307 F.3d 1351, 1361-63 (Fed. Cir. 2002), cert. denied, 539 U.S. 958 (2003).

Merck KGaA, found a pharmaceutical company's use of an amino acid sequence within the expressed experimental use exemptions of 35 U.S.C. § 271(e)(1), even though the use could be characterized as commercial.⁸

Since the early 1800s, the recognition of experimental use as a defense to patent infringement has continually evolved, allowing the defense for non-profit uses, characterizing such uses as *de minimis*, not recognizing the defense at all, or immunizing certain types of industry-specific experimental use by statute. In order to better understand recent experimental use holdings, a comprehensive review of common law experimental use and statutory interpretations of the 271(e) (1) experimental use exemption is necessary.

II. EXPERIMENTAL USE DEFENSE BEFORE *ROCHE v. BOLAR*

The right-granting provisions of the Patent Act of 1793 and the Patent Act of 1836 granted the patentee the full and exclusive right and liberty of "making, using, and vending" his patented invention.⁹ While patents no longer confer any rights to make or use anything, the words "making" and "using" have survived in the current patent law as actions a patentee can prevent others from doing.¹⁰

a. Actual Profit Infringement

Whittemore v. Cutter is credited with first recognizing the experimental use defense to patent infringement.¹¹ In the original suit, the court entered judgment for the plaintiff against the defendant's use of a patented machine that produced playing cards.¹² The defendant moved for a new trial, in part because of his objections to jury instructions that stated "making of a machine fit for use, and with a design to use it for profit" constituted infringement.¹³ Justice Story noted "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."¹⁴ Thus, the common law experimental use exception to patent infringement was born.

In *Sawin v. Guild*, the plaintiff held a patent on a machine for cutting brad nails. The deputy sheriff executed, seized and sold three such machines

8. See generally *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003), *vacated and remanded*, 545 U.S. 193, 208 (2005).

9. Patent Act, ch. 7, § 1, 1 Stat. 109-12 (1790).

10. 35 U.S.C. § 154(a)(1).

11. See *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

12. *Id.* at 1121.

13. *Id.*

14. *Id.*

in satisfaction of the then substantial debt of \$567.27.¹⁵ The plaintiff sued the deputy sheriff for infringement arising from the sale of his patented machines. Relying on the April 17, 1800, revision of the Patent Act of 1790, the plaintiff declared that "any person, without consent of the patentee . . . first obtained in writing, shall make, devise, use, or sell the thing, whereof the exclusive right is secured to the said patentee, such person, so offending, shall forfeit [the thing]."¹⁶ Justice Story expressed a policy concern that a party might be able to "lock up his whole property, however great, from the grasp of his creditors, by investing it in profitable patented machines."¹⁷ Story cited *Whittemore* as holding that "the making of a patented machine . . . must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification."¹⁸ However, Justice Story's view leaves open uses that are experimental in the near term, but intended for profit in the long term.

In *Byam v. Bullard*, Justice Curtis, besides expressing doubt regarding the experimental use theory, interpreted both *Whittemore* and *Sawin* as requiring plaintiff to show "injury and damage."¹⁹ This case also held that a sale to an agent of the patent owner was not an infringement because a sale to an agent would not deprive the patent owner of "the lawful rewards of his discovery," as stated in *Sawin*.²⁰

In *Poppenhusen v. New York Gutta Percha Comb Co.*, the defendant used the plaintiff's patented process to produce smooth and glossy surfaces on vulcanized rubber articles placed into the commercial market. The court instructed the jury that patent infringement occurs, and the experimental use doctrine is inapplicable, when "done as a matter of business, where the product of the experiment has been thrown into the market, to compete with the products of the plaintiff, although he may call it an experiment . . ."²¹ Here, as in *Sawin*, even though the facts of the case indicate profit, the holding does not expressly require profit to find infringement.²²

15. *Sawin v. Guild*, 21 F. CAS. 554, 554 (C.C.D. MASS. 1813) (No. 12,391).

16. *Id.*

17. *Id.* at 554-55.

18. *Id.* at 555.

19. *See id.*

20. *See id.*

21. *Poppenhusen v. New York Gutta Percha Comb Co.*, 19 F. CAS. 1059, 1063 (C.C.S.D. N.Y. 1858) (No. 11,283).

22. *See Sawin*, 21 F. CAS. at 555.

b. Possibility of Profit Infringement

In *Poppenhausen v. Falke*,²³ the court stated that it was “now well-settled that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee.”²⁴ This holding also reinforces the notion that experimentation performed by commercial entities for long-term profit can constitute an infringement.

In *Albright v. Celluloid Harness-Trimming Co.*,²⁵ the defendant abandoned experiments to perfect the manufacture of metal harness-trimmings coated with celluloid with plaintiff’s patented die. The court held that the use was a technical infringement and sufficient to authorize an injunction, even though it found neither damages incurred by plaintiff, nor profits incurred by defendant.²⁶ This is in contrast with Justice Curtis’s theory in *Byam v. Bullard*, that no action would lie except where “injury and damage” were shown.²⁷

In *Palmer v. United States*,²⁸ the Army manufactured 10,500 sets of the plaintiff’s patented knapsack, but found them unsatisfactory and never put them to “the test of actual use.” The court stated that the government had no right to make such a “huge experiment” and found it to be an act of patent infringement.²⁹

In *Beedle v. Bennett*, the Supreme Court held that a family’s use of a patented well on their property solely for personal convenience was an act of patent infringement.³⁰ This case leaves a question of whether using another’s patent to fulfill a physiological need, as opposed to philosophical taste, constitutes patent infringement.³¹ A physiological need requires some expenditure and a use of a patented invention and to avoid that expenditure would be denying the patent owner the lawful rewards of their discovery.³²

23. *Poppenhausen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D. N.Y. 1861) (No. 11,279).

24. *Id.*

25. *Albright v. Celluloid Harness-Trimming Co.*, 1 F. Cas. 320, 320 (C.C.N.J. 1877) (No. 147).

26. *Id.* at 323.

27. *Byam v. Bullard*, 4 F. Cas. 934, 935 (C.C.D. Mass. 1852) (No. 2,262).

28. *Palmer v. United States*, 20 Ct. Cl. 432 (1885), *aff’d*, 128 U.S. 262 (1888).

29. *Id.* at 437.

30. *Beedle v. Bennett*, 122 U.S. 71, 78 (1887).

31. *See id.*

32. *See id.*

c. Robinson on Patents 1890

Professor Robinson's famous 1890 treatise, *The Law of Patents for Useful Inventions*, firmly entrenched the experimental use exception into patent law when he wrote:

The interest of the patentee is represented by the emoluments which he does or might receive from the practice of the invention by himself or others. These, though not always taking the shape of money, are of a pecuniary character, and their value is capable of estimation like other property. Hence acts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one . . . the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind.³³

Robinson distinguishes experimental use from infringing use by considering whether the pecuniary interest of the patent owner is affected, and whether an accused infringer would be required to make a profit to constitute infringement.³⁴ Robinson defines experimental use as those that gratify scientific tastes, curiosity or amusement.³⁵ However, Robinson continues:

"But if the products of the experiment are *sold*, or used for the *convenience of the experimenter*, or if the experiments are conducted with a view to the *adaptation of the invention to the experimenter's business*, the acts of making or of use are violations of the rights of the inventor and infringements of his patent. In reference to such employments of a patented invention the law is diligent to protect the patentee, and even experimental uses will be sometimes enjoined though no injury may have resulted admitting of positive redress."³⁶

According to Professor Robinson, commercial use in the course of business for profit or for convenience of a patented invention constituted in-

33. 3 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 898 (Vol. 3 1890).

34. *Id.*

35. *Id.*

36. *Id.* (emphases added).

fringement by 1890.³⁷ In addition, Robinson recognized that damages were appropriate for infringement, even when it “results in no particular injury to the plaintiff, the commission of the wrong entitles him to some recovery in vindication of his invaded rights.”³⁸

d. In the Course of Business Infringement

In *Bonsack Mach. Co. v. Underwood*, defendant constructed a patented cigarette making machine to demonstrate the usefulness of his own patented improvement.³⁹ This was done for the purpose of selling his patent.⁴⁰ The court opined that “to constitute an infringement, the making must be with an intent to use for profit, and not for the mere purpose of a philosophical experiment.”⁴¹ The basis for the alleged infringement stemmed from defendant’s use of the patented machine to sell his own patent, gave an option to sell the machine, and helped organize a company to manufacture products with the machine: “A bill will lie for an injunction upon well-grounded proof of the intention to violate the patent right.”⁴² This holding is consistent with Robinson’s theory that a patent is infringed when experiments are conducted with a view to the adaptation of the invention to the experimenter’s business.⁴³

In *Clerk v. Tannage Patent Co.*, defendants claimed their nine-month use of plaintiff’s patented process for tanning skins and hides was experimental and conducted to determine the patented process’s utility.⁴⁴ In addition, the defendants claimed that the patented process had been publicly offered for license and therefore, they had special permission to make reasonable experiments and trials.⁴⁵ The Third Circuit affirmed a preliminary injunction to restrain infringement and held that in the absence of actual permission, even the expression of a willingness by the patent owner to sell a license under the patent did not confer a privilege to experimentally test.⁴⁶

In *Cimioti Unhairing Co. v. Derboklow*, the defendant used two patented machines for dehairing pelts for nearly three years, while claiming that he was only “experimenting . . . to see if he could not discover some improvement” that would be more effective.⁴⁷ The court rejected this argument

37. *Id.*

38. *Id.*

39. *Bonsack Mach. Co. v. Underwood*, 73 F. 206, 209 (C.C.N.C. 1896).

40. *Id.*

41. *Id.* at 211.

42. *Id.* at 211.

43. See ROBINSON, *supra* note 33, at § 898.

44. *Clerk v. Tannage Patent. Co.*, 84 F. 643, 643-44 (3d Cir. 1898).

45. *Id.* at 644.

46. *Id.*

47. *Cimotti Unhairing Co. v. Derboklow*, 87 F. 997, 999 (E.D.N.Y. 1898).

because the defendant dehaired pelts for customers in the ordinary course of business—a practice that “is not fairly within any legitimate use for experimental purposes only.”⁴⁸ Similar to *Clerk*, the use involved here was blatant prolonged commercial use and the products were actually sold for profit.

In *United States Mitis Co. v. Carnegie Steel Co.*, the defendant used a patented steel making process to manufacture 2,769 tons of armor plate from ingots for a period of three to four months.⁴⁹ The court rejected the defendant’s argument of experimental use, holding that “was a commercial use, extending over a period of several months and involved a very large product. It was in the course of business and for profit.”⁵⁰ By the turn of the century, the court looked not only at the type of use, such as commercial or scientific, but also the duration of use. Courts have consistently held that to avoid infringement, a purported experimental use must be brief.

The court in *Thompson v. Bushnell Co.* held that an infringer’s purpose and intent are immaterial to determine the question of infringement.⁵¹ This decision is contrary to *Whittemore’s* “with a design to use it for profit” definition of infringing use and *Sawin’s* “making with an intent to use for profit” caveat that constitutes infringing use.⁵² It is also contrary to the rationale expressed by Robinson; there, the court considered whether the alleged infringer conducted experiments with a view to the adaptation of the invention to the experimenter’s business. These criteria look directly to purpose and intent to determine if experimental use is infringing.

National Meter Co. v. Thomson Meter Co. held that intent was a relevant factor.⁵³ The defendant made six water meters covered by Plaintiff’s patent and sold one to Plaintiff.⁵⁴ The defendant argued that the sale was accidental, and moreover was “not employed for beneficial uses of a pecuniary character,” but were assembled for test purposes.⁵⁵ The court found sufficient evidence of threatened infringement and held that the defendant’s actions constituted infringement.⁵⁶ Since the court found sufficient intent, it declined to decide whether the tests and single sale constituted actual in-

48. *Id.*

49. *U.S. Mitis Co. v. Carnegie Steel Co.*, 89 F. 343, 346 (C.C.W.D. Penn. 1898), *aff’d without opinion*, 90 F. 829 (3d Cir. 1898).

50. *Id.* at 351.

51. *See generally* *Thompson v. Bushnell Co.*, 96 F. 238 (2d Cir. 1899).

52. *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (1813); *Sawin v. Guild*, 21 F. Cas. 554, 555 (1813).

53. *Nat’l Meter Co. v. Thomson Meter Co.*, 106 F. 531, 541-42 (C.C.S.D.N.Y. 1900).

54. *Id.* at 541.

55. *Id.*

56. *Id.* at 541-42.

fringement.⁵⁷ Evidently, *Thompson v. Busnell* was not followed in this decision.

In *Dowagiac Mfg. Corp. v. Minnesota Moline Plow Co.*, the court held that a patentee may be substantially injured because he has failed to collect at least a reasonable royalty, a just and deserved gain.⁵⁸ While the court did not provide a strong holding in regard to experimental use, the rationale is consistent with *Sawin*, where the court proposed that a patentee should not be deprived of “the lawful rewards of his discovery,” if lawful rewards are interpreted to include all the benefits that imbued with patent exclusivity monetary and otherwise.⁵⁹

In *Pairpearl Products, Inc. v. Joseph H. Meyer Bros.*, the defendant, purportedly for the purposes of experimentation, used a process of extracting pearl essence which was covered by plaintiff’s patent.⁶⁰ In addition, the defendants also claimed to have discovered a new agent used in its commercial process but refused to disclose the new agent’s composition at trial. The court found infringement, holding that the use was “large enough to be included in any accounting” and the defendants sold the resulting pearl essence “into commerce through the usual channels.”⁶¹

Kansas City Southern Ry Co. v. Silica Products held that an infringer’s purpose and intent are immaterial when determining the question of infringement.⁶² This holding is similar to *Thompson*. The court was likely reemphasizing the *Thompson* holding because intervening decisions addressing experimental use infringement seem to completely ignore *Thompson* in their decisions.

In *United States v. Dubilier Condenser Corp*, the court held that patent infringement is not a common law tort, but rather a creature of statute and should be governed by statute.⁶³ This decision rejects the common law concept of experimental use as first recognized in *Whittemore*. Implicit in this decision is the proposition that exceptions to patent infringement must first be defined by Congress and then interpreted by the courts.

e. Contributory Infringement

In *Ruth v. Stearns-Roger Mfg. Co.*, the defendant manufactured mining and milling machinery, resulting in a lawsuit for contributory infringement

57. *Id.* at 542.

58. *Dowagiac Mfg. Corp. v. Minn. Moline Plow Co.*, 235 U.S. 641, 648-49 (1915).

59. *Sawin*, 21 F. Cas. 554, 555.

60. *Pairpearl Prods., Inc. v. Joseph H. Meyer Bros.*, 58 F.2d 802, 802-04 (D. Me. 1932), *modified on other grounds*, 62 F.2d 668 (1st Cir. 1932).

61. *Id.* at 804.

62. *Kan. City S. Ry. Co. v. Silica Prods.*, 48 F.2d 503, 508 (8th Cir. 1931), *cert. denied*, 284 U.S. 626 (1931).

63. *United States v. Dublier Condenser Corp.*, 289 U.S. 178, 198-99 (1933).

because a purchaser continued infringement by using the products.⁶⁴ Today a purchaser would be exempt from a claim of contributory infringement.⁶⁵ The case involved two patented floatation machines and replacement parts sold to the Colorado School of Mines and used in its laboratory for experimental purposes.⁶⁶ The court held that, while the original sale to the School was an infringement, the sale of the recovery parts was not.⁶⁷ Furthermore, the court held that the “making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement,” but the sale of similar parts to other parties would be an infringement.⁶⁸ This case appears to suggest that the court did not view uses in a university laboratory as commercial and, therefore, within the experimental use exception. In addition, by today’s standards, since the university was not directly infringing, the parts supplier could not be held liable for contributing to infringement.⁶⁹

f. Commercial Use Continues to Infringe

Duplate Corp. v. Triplex Safety Glass Co. dealt with the infringement of Duplate’s laminated glass.⁷⁰ Although experimental use was not the focus of the case, the court suggested that a patentee may be substantially injured if he has failed to acquire the collection of at least a reasonable royalty.⁷¹ This is still in accordance with *Sawin*’s lawful reward theory.⁷²

64. *Ruth v. Stearns-Rogers Mfg. Co.*, 13 F. Supp. 697, 699 (D. Colo. 1935), *rev’d on other grounds*, 87 F.2d 35 (10th Cir. 1936).

65. Today this activity would not be labeled “contributory infringement.” 35 U.S.C. § 271(c) (2003) provides: “Whoever . . . imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.”

66. *Ruth*, 13 F. Supp. at 699, 703.

67. *Id.* at 713.

68. *Id.*

69. “[I]t is settled that if there is no direct infringement of a patent there can be no contributory infringement.” *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1961).

70. *Duplate Corp. v. Triplex Safety Glass Co.*, 298 U.S. 448 (1936), *superseded by statute*, 35 U.S.C. § 284 (2000), *as recognized in*, *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648 (1983).

71. *Id.* at 457.

72. *See Sawin v. Guild*, 21 F. Cas. 554, 614 (C.C.D. Mass. 1813).

In *RCA v. Andrea*, even though the defendant attempted to circumvent the plaintiff's patent by separating component parts within a single package before shipping, the court held that "sell[ing] all the elements of the completed patented combination" and combining components for testing prior to shipping was not experimental but commercial, and therefore infringement.⁷³ If tests were made to determine whether the parts were marketable or not, it is considered commercial, and therefore, infringing use.⁷⁴

g. The United States Infringes

In *Ordnance Engineering Corp. v. United States*, the court found that the manufacturing of shells covered by the plaintiff's patent was an infringement of that patent by the United States Navy Department.⁷⁵ However, the government was allowed to exclude 7,425 shells built for experimental purposes from the total number of shells the court found infringed on the plaintiff's patent; the court noted without citation that "experimental shells are shells built for experimental purposes."⁷⁶

h. Profit Again Required to Infringe

In *Akro Agate Co. v. Master Marble Co.*, during the course of research and development of a marble-making machine, the defendant experimented with a mechanism covered by the plaintiff's patent.⁷⁷ However, the defendant was unsatisfied with the results and abandoned the patented mechanism in favor of another method. The court held "[t]hat the experimental testing . . . for a brief period before going into commercial production . . . was not in law an act of infringement as marbles were not commercially sold."⁷⁸ This seems to support the proposition that commercially motivated experimental uses must be brief to avoid a finding of infringement.

i. Sales Demonstration Infringing

Sprout, Waldron & Co. v. Bauer Bros. Co. involved a defendant whose operation of manufactured machines infringed upon the plaintiff's patented manufacturing process.⁷⁹ Defendant kept the machines at a sales-demonstra-

73. *RCA v. Andrea*, 90 F.2d 612, 614 (2d Cir. 1937).

74. *Id.* at 614 (citing *Cimiotte Unhairing Co. v. Derboklow*, 87 F. 997 (C.C.N.Y. 1898)).

75. *Ordnance Eng'g Corp. v. United States*, 84 Ct. Cl. 1 (1936), *cert. denied*, 302 U.S. 708 (1937).

76. *Id.* at 1.

77. *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 315 (N.D. W. Va. 1937).

78. *Id.* at 333 (citing *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813)).

79. *Sprout, Waldron & Co. v. Bauer Bros. Co.* 26 F. Supp. 162, 165 (S.D. Ohio 1938).

tion laboratory and used them to make wood pulp and wall board for some of his customers.⁸⁰ Although the defendant did not claim experimental use as a defense, the court offered that “[t]he defendant cannot escape on the ground of experimental use where the machines were used to operate upon customers’ products in the ordinary course of business.”⁸¹

j. Design and Manufacturing Infringing Use

In *Northill Co. v. Danforth*, the defendant designed an anchor covered by plaintiff’s patent.⁸² Defendant had the anchors produced by various foundries and commercially sold them almost exclusively “to the Federal Government for use by the Army, Navy and Coast Guard.”⁸³ The defendant argued experimental use, claiming he only designed the anchor, and that an action of infringement would fail because there were “no civilian sales to make a prima facie case.”⁸⁴ The court rejected the defendant’s experimental use defense, observing that the “defendant’s experiments were evidently not made for philosophical or amusement purposes but were made in connection with his business as a manufacturer and salesman of anchors.”⁸⁵

k. A Prototype Seen as Experiment

In *Dugan v. Lear Avia, Inc.*, the defendant made radio direction-finding and position-indicating systems covered by plaintiff’s patent.⁸⁶ The court “eliminated from consideration” defendant’s prototype device because “it affirmatively appeared . . . that defendant built that device only experimentally and that it ha[d] neither manufactured it for sale nor sold any.”⁸⁷ This case seems to stand for the proposition that experiments are permissible, even if ultimately commercially motivated.

III. STATUTORY RECOGNITION OF EXPERIMENTAL USE

a. Atomic Energy Act of 1946

The Atomic Energy Act of 1946 authorized experimental and research activity by the newly created Atomic Energy Commission:

80. *Id.* at 165, 168-69.

81. *Id.* at 169.

82. *Northill Co. v. Danforth*, 51 F. Supp. 928, 929 (N.D. Cal. 1942), *modified on other grounds*, 142 F.2d 51 (9th Cir. 1944).

83. *Id.*

84. *Id.*

85. *Id.*

86. *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 224 (S.D.N.Y. 1944), *aff’d*, 156 F.2d 29 (2d Cir. 1946).

87. *Id.* at 229 (citing *Bonsack Mach. Co. v. Underwood*, 73 F. 206, 211 (C.C.N.C. 1896)).

for the conduct of research and developmental activities relating to 1) nuclear processes; 2) the theory and production of atomic energy, including processes and devices related to such production; 3) utilization of fissionable and radioactive materials for medical, biological, health, or military purposes; 4) utilization of fissionable and radioactive materials . . . for all other purposes, including industrial uses; and 5) the protection of health during research and production activities.⁸⁸

Additionally the Act encouraged experimental activity by the Atomic Energy Commission for studies of the social, political, and economic effects of the availability and utilization of atomic energy.⁸⁹ No case law is available to challenge the 1946 experimental authorizations. Therefore, in order to have experimental use recognized, industry-specific legislation had to be introduced.

b. Patent Act of 1952

An act of Congress approved July 19, 1952, effective January 1, 1953, substantially revised and codified patent laws into their present form.⁹⁰ Under § 154 of the Patent Act of 1952, which defines the rights conferred by a patent, the previous language was changed to “the right to exclude others from making, using, or selling the invention” in order to coincide with prior case law.⁹¹ This aligned the statute with the Supreme Court, which stated “all that the government conferred by the patent was the right to exclude others from making, using, or vending his invention.”⁹²

When Congress enacted the current revision of the patent laws, a statutory definition of patent infringement existed for the first time since the 1836 repeal of § 5 of the Patent Act of 1793.⁹³ Section 154 gives a patentee the right, *inter alia*, “to exclude others from making, using, or selling” a patented

88. Atomic Energy Act of 1946, ch. 724, 60 Stat. 755, 758 (1946).

89. *Id.* at 755.

90. Patent Act of 1952, ch. 905, 66 Stat. 792 (codified as amended in scattered sections of 35 U.S.C.).

91. *Id.* at 804.

92. *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 35 (1923) (citing *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405 (1908)). Also note that the scope of a patent claim might be wholly within the scope of an earlier unexpired patent claim; hence the recipient of the later claim could not practice any subject matter within his claim, except by permission of the holder of the broader claim. For example, a claim might recite the combination of A-B-C, but B might have been the subject of an earlier unexpired patent. The holder of the A-B-C claim is blocked from practicing that combination without the assent of the B patentee.

93. *See* 66 Stat. at 792.

invention.⁹⁴ Section 271(a) of the code defined infringement as “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.”⁹⁵ The Patent Act of 1952 made no statutory exemptions for experimental use; however, it did provide that damages shall be “in no event less than a reasonable royalty for the use made of the invention by the infringer.”⁹⁶

c. Atomic Energy Act of 1954

The Atomic Energy Act of 1954 eliminated the experimental exemption contained in the 1946 version of that act for research activity relating to atomic energy.⁹⁷ By 1954, there was no statutory recognition, either general or industry-specific, of the experimental use defense to patent infringement by private parties.⁹⁸

IV. EXPERIMENTAL USE BRIEFLY RESURRECTED

a. Royalty-Free Experimental Use Recognized for United States

The United States was recognized as a royalty-free experimental user in *Chesterfield v. United States*.⁹⁹ The patent holder of a metal alloy sued the United States for compensation from the government’s use of the patent. The Court of Claims held that although the government used 3,679 pounds of the alloy, there was no liability to the patent holder because “the evidence shows that a portion of the . . . alloy procured by the defendant was used only for testing and for experimental purposes, and there was no evidence that the remainder was used other than experimentally.”¹⁰⁰ What remained to be seen was if an experimental use could be recognized in the private sector as well.

94. 35 U.S.C. § 154 (2002).

95. 35 U.S.C. § 271(a). Also note that 35 U.S.C. § 283 states that “the several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.”

96. 35 U.S.C. § 284.

97. See 42 U.S.C. §§ 2181-90.

98. The immunity provided to the U.S. government by 28 U.S.C. § 1498 would also apply to government contractors if two criteria are met: (1) the use is “for the Government”; and (2) the Government gives “its authorization or consent” for the use. *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 897–98 (Ct. Cl. 1976). The government cannot be enjoined from infringing a patent, but it may have to pay compensation for doing so. But this minimal liability can disappear, as shown in the next section.

99. See *Chesterfield v. United States*, 159 F. Supp. 371, 375 (Ct. Cl. 1958).

100. *Id.*

b. Private Sector Experimental Use

In *Kaz Manufacturing v. Chesebrough-Ponds, Inc.*, the defendant created a hybrid steam vaporizer from a number of the plaintiff's patented machines and used it in a television commercial for the defendant's competing aerosol product.¹⁰¹ The Second Circuit affirmed a lower court finding of no infringement and held that the purpose of an accused making or use "may determine whether the construction constitutes an infringement of the patentee's rights."¹⁰² In terms of experimental use, this could be interpreted as *Whittemore* dicta in that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."¹⁰³ In terms of the use in advertising, Robinson's treatise explains that "where it is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or *for amusement*, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind."¹⁰⁴

V. COMMERCIAL USE STILL INFRINGING

In *Spray Refrigeration Co. v. Sea Spray Fishing, Inc.*, the defendant used the plaintiff's patented method for freezing fish onboard a vessel at sea on one or two fishing voyages.¹⁰⁵ The defendant contended that the use was "only for the purpose of experimentation as to the desirability of using this method" and found that satisfactory results could be obtained without using the process.¹⁰⁶ The Ninth Circuit found that the defendant had infringed, distinguishing earlier holdings in *Chesterfield* and *Dugan*, noting that "in neither of those cases was the experimental use coupled with a commercial use."¹⁰⁷ This decision accords with *Whittemore's* "with a design to use it for profit" definition of infringing use and *Sawin's* "making with an intent to use for profit."¹⁰⁸ It is also in line with Professor Robinson's treatise in that "if

101. *Kaz Mfg. v. Chesebrough-Ponds, Inc.*, 317 F.2d 679 (2d Cir. 1963).

102. *Id.* at 680.

103. *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

104. 3 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 898 at 56 (1890) (emphasis added).

105. *Spray Refrigeration Co. v. Sea Spray Fishing, Inc.*, 322 F.2d 34, 36 (9th Cir. 1963).

106. *Id.*

107. *Id.*

108. *Whittemore*, 21 F. Cas. at 1121; *Sawin*, 21 F. Cas. at 555.

the products of the experiment are sold . . . the acts of making or of use are violations of the rights of the inventor and infringements of his patent.”¹⁰⁹

The courts in both *Aro Manufacturing Co. v. Convertible Top Replacement Co.* and *Coakwell v. United States* held that it was established law that the use of a patented invention, without either manufacture or sale, is actionable.¹¹⁰ Thus, the patentee does not need to have any evidence of damage or lost sales to bring an infringement action.

VI. *DE MINIMIS* EXPERIMENTAL USE NOT INFRINGING

In *Finney v. United States*, the holder of a patented glove sued the United States for infringement.¹¹¹ The defendant admitted using the patented glove in conjunction with an interlocking handle in an experiment with a NASA astronaut.¹¹² The trial judge of the Court of Claims denied a motion by the government for summary judgment of noninfringement, ruling that “whether or not NASA’s allegedly single use was an experimental one, is a question of fact that can only be resolved after a trial on the merits.”¹¹³ The judge at trial found that the doctrine of *de minimis non curat lex* (the law is not concerned with trifles) applied.¹¹⁴ The case supports the doctrine that experimental use is *de minimis* use. This may have been how Justice Curtis was interpreting *Whittemore* and *Sawin* in his *Byam v. Bullard* opinion based on the principle that no action would lie except where “injury and damage” were shown.¹¹⁵

In *Douglas v. United States*, the United States bought six airplanes and eleven replacement engines covered by the plaintiff’s patents, and the Army, Navy, Air Force and NASA used them over a four-year period.¹¹⁶ The trial judge reviewed the prior cases on experimental use and noted “the defense is nothing more than an expression of the maxim *de minimis non curat lex*.”¹¹⁷ Federal courts have found that the use of accused devices is not experimental when the defendants have never been authorized to use the patent holder’s devices for their own purposes and interests, especially if “there was a pattern of systematic exploitation, extending over a prolonged period” along with an absence of the use simply being “for amusement, to satisfy idle curi-

109. 3 ROBINSON, *supra* note 93, at 56.

110. See *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484 (1964); *Coakwell v. United States*, 372 F.2d 508, 510 (Ct. Cl. 1967).

111. *Finney v. United States*, 178 U.S.P.Q. 235, 235-36 (Ct. Cl. 1973).

112. See *id.* at 236.

113. *Id.* at 237.

114. *Finney v. United States*, 188 U.S.P.Q. 33, 35 (Ct. Cl. 1975).

115. *Byam v. Bullard*, 4 F. Cas. 934, 935 (C.C.D. Mass. 1852).

116. *Douglas v. United States*, 181 U.S.P.Q. 170, 177 (Ct. Cl. 1974).

117. *Id.*

osity, or for philosophical inquiry.”¹¹⁸ But in *Douglas v. United States*, the Court of Claims subsequently affirmed in favor of the defendant solely on invalidity grounds.¹¹⁹ This decision further supports a separate doctrine of experimental use as *de minimis* use, and possible determining factors drawn from this case include: 1) pattern of use, 2) length of period of use, 3) amount used, and 4) purpose of use.¹²⁰

In *Pitcairn v. United States*, the defendant United States manufactured seven models of helicopters, and the court agreed with the claims of infringement on eleven of the plaintiff’s patents.¹²¹ Although the defendant urged the court “to exclude from compensation any aircraft used by the defendant for testing, evaluational, demonstrational or experimental purposes,” the trial judge held that “[t]ests, demonstrations, and experiments of such nature are intended uses of the infringing aircraft manufactured for the defendant and are in keeping with the legitimate business of the using agency. Experimental use is not a defense in the present litigation.”¹²²

The judge relied on *Douglas* and distinguished *Chesterfield*—in that case, the government “procured by purchase, not by manufacture.”¹²³ This decision also accords with *Whittemore*’s “with a design to use it for profit” definition of infringing use and *Sawin*’s “making with an intent to use for profit.”¹²⁴ It is also in line with Professor Robinson’s view that if “used for the convenience of the experimenter, or if the experiments are conducted with a view to the adaptation of the invention to the experimenter’s business the acts of making or of use are violations of the rights of the inventor and infringements of his patent.”¹²⁵

VII. SUMMARY PRE-1984 COMMON LAW EXPERIMENTAL USE DEFENSE

Commercialism and intent to profit seem to be the deciding factors. The experimental use exemption is only allowed by industry-specific statutorily defined exemptions, or if the use is considered *de minimis*.

118. *Id.*

119. *Douglas v. United States*, 510 F.2d 364 (Ct. Cl. 1975).

120. *See Douglas*, 181 U.S.P.Q. at 177.

121. *Pitcairn v. United States*, 188 U.S.P.Q. 35, 46-47 (Ct. Cl. 1975).

122. *Id.* at 47.

123. *Pitcairn v. United States*, 547 F.2d 1106, 1125 (Ct. Cl. 1976).

124. *Whittemore*, 21 F. Cas. at 1121; *Sawin*, 21 F. Cas. at 555.

125. 3 ROBINSON, *supra* note 98, at 56 (emphasis added).

**VIII. ROCHE PRODUCTS, INC. v. BOLAR PHARMACEUTICAL CO., INC.
(FED. CIR. 1984)**

a. Roche

In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, the plaintiff held a patent on flurazepam hydrochloride, the active ingredient in its prescription Dalmane sleeping pill.¹²⁶ The defendant, Bolar, used flurazepam hydrochloride to perform tests that were needed to obtain Food and Drug Administration (FDA) approval for Bolar's generic version prior to the plaintiff's patent expiration on January 17, 1984.¹²⁷ The district court held that there was no infringement because the use was *de minimis* and experimental; therefore, the district court was in line with the pre-1984 court decisions dealing with experimental use.¹²⁸ However, the Federal Circuit reversed, holding that even if Bolar's use was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval, it was "solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."¹²⁹ Since there was "a violation of the rights of the patentee to exclude others from using his patented invention," the Federal Circuit held that the Court of Claims precedents such as *Pitcairn* were controlling.¹³⁰

b. 35 U.S.C. § 271(e)(1)

The problem with the *Roche* decision is that the combined effect of the patent law and the FDA regulatory approval requirements effectively extended the patent term.¹³¹ In response, Congress immediately passed the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.¹³² Section 202 of this legislation enacted 35 U.S.C. § 271(e)(1), providing that making, using, or selling, and offering to sell or importing of "a patented invention," was not an act of infringement if the act be "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."¹³³ As with the Atomic Energy Act of 1946, industry specific legislation had to be intro-

126. *Roche Prod., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 860 (Fed. Cir. 1984).

127. *Id.*

128. *See id.* at 861.

129. *Id.* at 863.

130. *Id.*

131. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990).

132. *See* 35 U.S.C. § 271(e)(1) (2000)) (referred to as the HATCH-WAXMAN ACT because of the two primary sponsors, Senator Orrin Hatch (R- UT) and Congressman Henry Waxman (D-CA)).

133. 35 U.S.C. § 271(e).

duced in order to define certain specific experimental use exemptions to patent infringement. Unlike the 1946 act, litigation proliferated relating to the § 271(e) experimental exemption.

The first case, *Eli Lilly & Co. v. Medtronic, Inc.*, involved the question of whether the § 271(e)(1) exemption applied literally, that is, to experiments needed for regulatory approval under a statute regulating drugs, even if the item in question was not itself a drug. In the instant case it was a medical device—an implantable defibrillator.¹³⁴ The appeals court held that the exemption was not limited to drugs, but extends to medical devices that are likewise subject to Food and Drug Administration approval under the Food Drug and Cosmetic Act, which also regulates drugs.¹³⁵ The Supreme Court affirmed, with Justice Scalia noting that “[t]he phrase ‘patented invention’ in § 271(e)(1) is defined to include all inventions where regulatory approval is needed pursuant to the statute, not drug-related inventions alone.”¹³⁶

c. Possibility of Commercialism Still Infringing with § 271(e)(1)

In *Deuterium Corp. v. United States*, the situation involved only case-law doctrine and did not involve FDA approvals.¹³⁷ During a 120-hour test run at a “pilot” plant, a government contractor tested its steam cleaning process to remove hydrogen sulfide from geothermal steam. The Claims Court held that the experimental use exception was not applicable because the pilot had none of “the hallmarks of an experiment conducted for curiosity, amusement, or intellectual stimulation.”¹³⁸ Instead, “any experimentation motivated by curiosity, amusement, or general intellectual inquiry took place long before creation of the detailed and expensive proposal for a pilot project.”¹³⁹ Further, the court stated that “if fully successful, the pilot could have paved the way for broader commercial applications,” and concluded by noting that for a brief period of time, steam processed at the facility generated commercial electricity.¹⁴⁰ The Claims Court noted that, although Congress narrowed application of the doctrine affecting reporting requirements for federal drug laws, Congress did not disturb the Federal Circuit’s enunciation of the parameters of the experimental use exception.¹⁴¹

134. *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 404 (Fed. Cir. 1989), *reh’g denied*, 879 F.2d 849, *aff’d*, 496 U.S. 661.

135. *Id.* at 406.

136. *Eli Lilly*, 496 U.S. at 665.

137. *See Deuterium Corp. v. United States*, 19 Cl. Ct. 624 (1990).

138. *Id.* at 634.

139. *Id.*

140. *Id.* at 634.

141. *Id.* at 632, n.14.

d. § 271(e)(1) Exemption Broadened

In *Intermedics, Inc. v. Ventritex, Inc.*, the Northern District of California held that any commercial uses that went beyond what § 271(e)(1) protects, such as trade show demonstrations and demonstrations to persons who were not screened for eligibility, were *de minimis*.¹⁴² The court noted that 1) a patentee may not eliminate the § 271(e)(1) exemption merely by showing that the accused manufacturer “*intends to commercialize the device before the expiration of the allegedly infringed patent,*”¹⁴³ and 2) the § 271(e)(1) exemption “is not lost simply as a result of a showing that the [accused infringer] has engaged in *non-infringing acts* whose ‘uses’ fall outside those permitted by the statute.”¹⁴⁴ The district court further held that a court should not allow a patentee to pursue a patent validity and infringement declaratory judgment suit against a party whose current activity § 271(e)(1) protects.¹⁴⁵

In *Teletronics Pacing Systems, Inc. v. Ventritex, Inc.*, pursuant to a Food and Drug Administration Investigational Device Exemption, Ventritex began clinical trials of its implantable defibrillator.¹⁴⁶ The Investigational Device Exemption enabled it to sell its device at cost for patient implantation to gather data that the FDA required for market approval. Ventritex also demonstrated its device to physicians and non-physicians at medical conferences and described its clinical trial results to investors, analysts, and journalists. Teletronics sued, asserting that the Ventritex’s activities exceeded the § 271(e)(1) exemption, and sought a declaratory judgment of infringement upon the expiration of the exemption. The district court dismissed, and the appeals court affirmed, noting that § 271(a) of the Patent Act “clearly specifies only the making, using or selling of a patented invention as infringing activities.”¹⁴⁷ Under § 271(e)(1), these potentially infringing activities are exempt if performed solely for uses reasonably related to the development of information for FDA approval.¹⁴⁸ The Federal Circuit, approving the analysis in *Intermedics*, held that the § 271(e)(1) exemption is not lost because a party, who has made no use of the patented invention other than for FDA-related data gathering, disseminates the data for business and fund-raising purposes.¹⁴⁹

142. *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1277-78 (N.D. Cal. 1991), *aff’d*, 991 F.2d 808 (Fed. Cir. 1993).

143. *Id.* at 1273 (emphasis in original).

144. *Id.* at 1278.

145. *Id.* at 1290.

146. *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992).

147. *Id.* at 1523.

148. *Id.*

149. *Id.* at 1525.

In *Farmaceutisk Laboratorium Ferring A/S v. Solvay Pharmaceuticals, Inc.*, the Northern District of Georgia held that a defendant accused of infringement may pursue a declaratory judgment counterclaim as to patent invalidity, but not as to noninfringement, because the defendant's current clinical testing uses of plaintiff's patented disease treatment method were protected from an infringement claim by § 271(e)(1).¹⁵⁰

In *Infinitech, Inc. v. Vitrophage, Inc.*, the Northern Indiana District Court upheld a potential infringer's declaratory judgment action on validity even though the patentee conceded that the plaintiff's current activities were exempt under § 271(e)(1).¹⁵¹ "When the declaratory plaintiff is a patent holder seeking a ruling of infringement against a product still in clinical testing, the purposes of the Act and of Section 271(e)(1) are not undermined by holding that jurisdiction does not attach until after the allegedly infringing product moves beyond clinical testing."¹⁵² This case is also notable for upholding jurisdiction over the case under the reasonable-apprehension-of-suit standard then in effect.¹⁵³

In *Abtox, Inc. v. Exitron Corp.*, Abtox had a patent on a device for sterilizing medical instruments.¹⁵⁴ Exitron argued that the use of its version of the device was exempt from infringement under § 271(e)(1) because it was using the class II medical device in order to obtain FDA approval. However, Abtox argued that Exitron's use did not fall within the scope of § 271(e)(1) because class II medical devices are not eligible for patent term extensions. The court upheld the broad holding of *Eli Lilly*, agreeing that "section 271(e)(1) applies to any use reasonably related to regulation under the FDCA."¹⁵⁵ The device before the Supreme Court in *Eli Lilly* was a class III medical device, a type of device which is eligible for patent term extension and premarketing approval requirements.¹⁵⁶ The Federal Circuit further broadened the scope of § 271(e)(1) by holding that although class II medical devices are not eligible for patent term extension, they are nonetheless subject to the § 271(e)(1) exception.¹⁵⁷

150. *Farmaceutisk Laboratorium Ferring A/S v. Solvay Pharm., Inc.*, 25 U.S.P.Q. 2d 1344, 1353 (N.D. Ga. 1992).

151. *Infinitech, Inc. v. Vitrophage, Inc.*, 30 U.S.P.Q. 2d 1201 (N.D. Ind. 1994).

152. *Id.* at 1205.

153. *See Infinitech, Inc. v. Vitrophage, Inc.*, 842 F. Supp. 332, 337-38 (N.D. Ill. 1994).

154. *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1020-21 (Fed. Cir. 1997).

155. *See id.* at 1028; *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 664 (1990).

156. *Eli Lilly*, 496 U.S. at 670; *see also* 35 U.S.C. 156 (2000).

157. *See Abtox*, 122 F.3d at 1028-29.

e. Experimental or *De Minimis* Uses with Commercialism Infringes

In *Embrex, Inc. v. Service Engineering Corp.*, Embrex owned a patent on a method for inoculating birds against disease by injecting vaccines into a specified region of the egg before hatching.¹⁵⁸ Service Engineering unsuccessfully attempted to design around the Embrex patent by building an injection machine outside the patent and hiring two scientists to investigate the possibility of injecting chicken embryos outside the region of the egg covered by the patent. Even with this patent-law-savvy experimental approach, the activities were found to infringe because injecting the eggs with a vaccine was done expressly for commercial purposes and therefore was not experimental use nor *de minimis*.¹⁵⁹ Furthermore, even though Service Engineering did not sell any injection machines or commercially practice the patented method, the court did not allow the exemption.¹⁶⁰ Judge Rader's concurring opinion expressed his view that the Patent Act "leaves no leeway to excuse infringement because the infringer only infringed a little."¹⁶¹ Since Judge Rader had defined experimental use as a plea based on the "intent" of the infringing activity, he concluded that recent cases had eliminated the experimental use exemption completely, even in the instances of noncommercial and idle curiosity uses.¹⁶²

f. Broad Reach of 271(e)(1) Continues To Be Found

In *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, the Southern District Court of New York expanded the scope of § 271(e)(1) to include patented research tools used in the course of developing drugs for clinical trials ultimately intended for FDA approval.¹⁶³ The court further noted that the activity need only be likely to generate information relevant to an FDA filing, even if this information is never actually used to obtain FDA approval.¹⁶⁴

In *Scripps Clinic & Research Foundation v. Genentech, Inc.*, the Scripps Clinic owned patents on a method of preparing the agent Factor VIII:C by purifying and concentrating human or porcine blood plasma.¹⁶⁵ The Northern District of California noted that the legislative history of the

158. *Embrex, Inc. v. Service Eng'g Corp.*, 216 F.3d 1343, 1346 (Fed. Cir. 2000).

159. *Id.* at 1349.

160. *Id.*

161. *Id.* at 1353 (Rader, J., concurring) (citing *Deuterium*, 19 Cl. Ct. at 631).

162. *Id.*

163. *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 2001 U.S. Dist. LEXIS 19361, at *5 (S.D.N.Y. Nov. 27, 2001).

164. *Id.*

165. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1383 (N.D. Cal. 1987).

statute indicated that the only acceptable use of the patented invention under § 271(e)(1) is bioequivalency testing for FDA approval.¹⁶⁶ The court pointed out that Genentech's use of the protein was not solely for the purpose of development and submission of information to the FDA but Genentech also used the protein to develop a more efficient and less costly manufacturing process and to obtain a foreign patent.¹⁶⁷ This narrow interpretation of the scope of § 271(e)(1) continued in *Ortho Pharmaceutical Corp. v. Smith*, where the district court held that § 271(e)(1) was limited "to permitting generic manufacturers to establish the bioequivalency of generic drugs" and did not permit any other collateral uses such as using the FDA data to promote or market the product.¹⁶⁸ This narrow interpretation of § 271(e)(1) uses was unpopular among other courts and lasted a brief period of time.

In *Intermedics v. Ventritex*, Ventritex used the clinical trial data obtained under the protection of § 271(e)(1) to solicit money to fund further clinical trials after the patent term expired; Ventritex also used this data to obtain patent rights in other countries.¹⁶⁹ The court noted that an otherwise infringing activity is exempt if:

It [would] have been reasonable, objectively, for a party in defendant's situation to believe that there was a decent prospect that the "use" in question would contribute (relatively directly) to the generation of kinds of information that was likely to be relevant in the processes by which the FDA would decide whether to approve the product[.]¹⁷⁰

Thus, the court held Ventritex's uses did not infringe, and the Federal Circuit affirmed the district court's decision, suggesting that Congress intended that § 271(e)(1) be used to shelter all products seeking FDA approval, regardless of their projected commercialization date.¹⁷¹

IX. MADEY—NO COMMON LAW EXPERIMENTAL USE EXEMPTION FOR UNIVERSITIES

In *Madey v. Duke University*, Madey was a tenured faculty member and director of a physics research laboratory at Duke University and owned a patent on a free-electron laser (FEL) oscillator which was used as a spectroscopy research tool.¹⁷² After Madey left his position, Duke continued to use

166. *Id.* at 1396.

167. *Id.*

168. *Ortho Pharm. Corp. v. Smith*, 18 U.S.P.Q. 2d 1977, 1992 (E.D. Penn. 1990).

169. *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269 (N.D. Cal. 1991).

170. *Id.* at 1280.

171. *Intermedics*, 26 U.S.P.Q. 2d at 1528.

172. *Madey v. Duke University*, 307 F.3d 1351, 1352 (Fed. Cir. 2002).

the FEL oscillator.¹⁷³ Madey sued Duke for patent infringement and Duke defended, claiming that its use of the FEL oscillator was an experimental use.¹⁷⁴ The district court agreed with Duke and held that the experimental use defense covered uses “solely for research, academic, or experimental purposes.”¹⁷⁵ But on appeal, the Federal Circuit held that the district court’s definition of experimental use was too broad and stated that any use which has the “slightest commercial implication” or is “in keeping with the legitimate business of the alleged infringer” cannot qualify for the experimental use defense.¹⁷⁶ Duke’s nonprofit status did not persuade the court, but rather Duke’s use unmistakably furthered Duke’s “legitimate business objectives” which included “educating and enlightening students and faculty” and enhancing the status of the university; therefore Duke’s use of the FEL oscillator did not fall within the experimental use exemption.¹⁷⁷

Almost 200 years after *Whittemore*, a simple straight forward commercialism argument is still being used to defeat an experimental use argument. Today, colleges and universities are permitted to be patent machines, generate enormous income, and profit from patent ownership.¹⁷⁸ If the *Roche* holding is allowed to stand, research will be hindered. If there is no safe way to experiment on patented inventions, it will be the sole domain of the original patentee to make improvements on the original invention. The original patentee may have a right to equivalents and obvious enhancements to their invention, but not a monopoly on all future improvements.

X. *INTEGRA*—271(e)(1) BROAD ENOUGH TO INCLUDE COMMERCIAL EXPERIMENTAL USES

Recently, in *Integra Lifesciences I, Ltd. v. Merck KGaA*, Integra had several patents on a pharmacologically useful “short tri-peptide segment of fibronectin” with the amino acid sequence Arg-Gly-Arg, known as the RGD peptide.¹⁷⁹ Merck hired Dr. David Cheresh, a scientist at Scripps Research Institute, to investigate compounds with the same receptor blocking capability as the RGD peptides.¹⁸⁰ Eventually, Integra offered to license their pat-

173. *Id.* at 1353.

174. *Id.*

175. *Id.* at 1355.

176. *Madey*, 307 F.3d at 1361-62.

177. *Id.*

178. Bayh-Dole Act of 1980, H.R. 6933, P.L. No. 96-517 (1980) (codified as amended at 35 U.S.C. § 202(a) (2000)) (allows universities and other non-profit institutions to retain ownership of patents from federally-funded research).

179. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 862 (Fed. Cir. 2003).

180. *Id.* at 863.

ents to Merck but Merck ultimately declined the offer; subsequently, Integra sued Merck, Scripps, and Dr. Cheresch for patent infringement.¹⁸¹ Merck claimed that its use of the RGD peptides in preclinical studies was exempt as within the scope of 35 U.S.C. § 271(e)(1).¹⁸² The district court held that the § 271(e)(1) exemption failed to cover the work performed for Merck at Scripps because it was not objectively reasonable that this work would be relevant to FDA approval.¹⁸³

The Federal Circuit affirmed the district court's holding on the ground that the § 271(e)(1) safe harbor did not apply because "the Scripps work sponsored by Merck was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds."¹⁸⁴ Most notable, however, is Judge Newman's dissenting opinion where she indicates that she would have found that Merck did not commit infringement because its activities were *either* within the common law experimental use exception *or* were immunized by § 271(e)(1).¹⁸⁵ Newman stated that allowing this type of experimental research "is essential to the creation of new knowledge" and therefore is essential to promoting "scientific and technologic progress."¹⁸⁶ Perhaps the Newman approach signaled a return to a broad experimental use exemption that is not tied to FDA activities.

The Supreme Court unanimously reversed the Federal Circuit's decision, commenting that "as an initial matter, we think it apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA."¹⁸⁷ According to the Supreme Court, "[t]his [information] necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process."¹⁸⁸ To construe § 271(e)(1) as the Federal Circuit did "is effectively to limit assurance of exemption to the activities necessary to seek approval of a generic drug."¹⁸⁹

The *Integra* decision had a very different outcome from *Madey*, possibly because *Integra* interpreted a statutorily defined experimental exemption in conjunction with nearly two decades of case law. Commercial uses were contemplated by the legislature when § 271(e)(1) was enacted and courts

181. *Id.*

182. *Id.* at 86.

183. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 200 (2005).

184. *Integra*, 331 F.3d at 866.

185. *Id.* at 878 (Newman, J., concurring in part, dissenting in part).

186. *Id.* at 876.

187. *Merck*, 545 U.S. at 202.

188. *Id.*

189. *Id.* at 206.

have read § 271(e)(1) as broadly as written, to allow for products and uses not originally contemplated to be more acceptable in the scientific industry. On the other hand, universities lack statutorily defined experimental exemptions in patent law. Also lacking is extensive case law dealing specifically with universities and common law experimental exemptions. Therefore, despite their non-profit status, universities must be characterized as a commercial entity and analyzed using common law experimental use case law for other commercial entities.

Historically, common law experimental use was rarely accepted as a defense to patent infringement. Until recently, even statutorily defined industry specific experimental exemptions had to overcome a strong bias against commercialism, making the experimental defense invalid. The experimental hands of universities and non-profit research organizations can only be untied if they are provided with statutorily defined experimental exemptions in patent law. Once non-profit and universities experimental exemptions are provided, they must be narrowed and broadened in court to determine the acceptable commercial uses that can still be deemed as experimental.

XI. CONCLUSION

The holdings of *Integra* and *Madey* can be explained by an historical analysis of the experimental use as a defense or an exemption to patent infringement. Experimental use of a patented invention was initially limited to non-profit uses not in the regular course of business, for amusement, or to satisfy idle curiosity. Before 271(e)(1) and the holding in *Integra*, courts rarely allowed the common law experimental use defense to include commercial, for-profit uses. The *Madey* holding can be read as redefining a non-profit organization's activities as commercial and then rejecting the experimental use defense under common law. The *Integra* holding can be read as allowing commercial experimental use for FDA approval as provided by statute.

Does the experimental use defense to patent infringement still exist today? The answer is both yes and no. No, in terms of common law experimental use, which case history has shown that courts are reluctant to apply. Yes, in terms of well-defined, industry-specific experimental use exemptions defined by statute. Moving forward, it will be necessary for other industries, such as universities and non-profit research organizations, to lobby for statutes that specifically define experimental exemptions.